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1805 Rec'd PCT/PTO 22 MAR 2002

FORM PTO-1390 (REV. 12-2001) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 1805

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/088954

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/AU00/01159	25 September 2000	24 September 1999; 16 November 1999

TITLE OF INVENTION: SIDE EFFECTS TREATMENT

APPLICANT(S) FOR DO/EO/US: David Rudov

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [ ] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [X] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [XX] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [ ] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [XX] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98. including references
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [X] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [X] Other items or information:
    1. Application Data Sheet
    2. Return Receipt Postcard

10/088954 JC13 Rec'd PCT/PTO 22 MAR 2002

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/088954	PCT/AU00/01159	1805

21. [X] The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 1,040.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [X] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	31 - 20 =	11	x **$18.00**	$ 198.00	
Independent claims	6 - 3 =	3	x **$84.00**	$ 252.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$280.00**	$ 280.00	
TOTAL OF ABOVE CALCULATIONS =				$ 1,900.00	
[X] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			+	$	
SUBTOTAL =				$ 950.00	
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE =				$ 950.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
TOTAL FEES ENCLOSED =				$ 950.00	
				Amount to be refunded:	$
				charged:	$

a. [X] A check in the amount of $ 950.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 13-1940 . A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Timothy J. Martin, P.C.
9250 W. 5th Avenue, Suite 200
Lakewood, Colorado 80226
(303) 232-3388

SIGNATURE

Michael R. Henson
NAME

39,222
REGISTRATION NUMBER

Application Data Sheet

Application Information

Application Type::	Regular
Subject Matter::	Utility
Title::	Side Effects Treatment
Attorney Docket Number::	1805
Request for Early Publication::	No
Request for Non-Publication::	No
Small Entity::	Yes

Applicant Information

Applicant Authority type::	Inventor
Primary Citizenship Country::	Australia
Status::	Full Capacity
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Middle Name::	
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State or Province of Residence::	Victoria
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Postal or Zip Code of mailing address::	3000

Correspondence Information

Correspondence Customer Number:: 24264

Representative Information

Representative Customer Number:	24264

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	35 U.S.C. 371 of	PCT/AU00/01159	09/25/2000
PCT/AU00/01159	Claims benefit of	PQ 3050	09/24/1999
PCT/AU00/01159	Claims benefit of	PQ 4064	11/16/1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	David Rudov
App. No.:	
International App. No.:	PCT/AU00/01159
International Filing Date:	25 September 2000
Docket No.:	1805
Title:	***SIDE EFFECTS TREATMENT***
Art Unit:	
Examiner:	
Action:	***PRELIMINARY AMENDMENT***
Date:	March 22, 2002

TO: Box PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please amend the above-identified patent application as follows:

In the Specification:

In accordance with 37 C.F.R. §1.121(b)(1)(i) and (ii), please add the following headings in the specification:

On page 1, after the title, kindly insert the heading "FIELD OF THE INVENTION";

On page 1, after line 3, kindly insert the heading "BACKGROUND OF THE INVENTION";

On page 2, after line 16, kindly insert the heading "BRIEF SUMMARY OF THE INVENTION";

On page 3, after line 11, kindly insert the heading "DETAILED DESCRIPTION OF THE INVENTION"

Also in accordance with 37 C.F.R. §1.121(b)(1)(i) and (ii), please add the following paragraph after page 10, line 20:

Accordingly, the present invention has been described with some degree of particularity directed to the exemplary embodiments of the present

invention. It should be appreciated, though, that the present invention is defined by the following claims construed in light of the prior art so that modifications or changes may be made to the exemplary embodiments of the present invention without departing from the inventive concepts contained herein.

In the claims:

In accordance with 37 C.F.R. §1.121(c)(1), please cancel claims 13-22.

In accordance with 37 C.F.R. §1.121(c)(1)(i), a clean version of amended claims 4-7, 9-12, 25, 26, 28, 30-33 and 35 is as follows:

4. (Amended) The use as claimed in claim 1 or claim 2 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

5. (Amended) The use as claimed in claim 1 or claim 2 wherein the liquid extract comprises substantially only the water soluble components of the juice.

6. (Amended) The use as claimed in claim 1 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

7. (Amended) A product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the product comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

9. (Amended) A product as claimed in claim 8 wherein the juice is derived from rye grass (Secale Cereale).

10. (Amended) A product as claimed in claim 7 or claim 8 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

11. (Amended) A product as claimed in claim 7 or claim 8 wherein the liquid extract comprises substantially only the water soluble components of the juice.

12. (Amended) A product as claimed in claim 8 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

25. (Amended) An adjunct secondary treatment substance as claimed in claim 23 wherein the liquid extract comprises substantially only the water soluble components of the juice.

26. (Amended) An adjunct secondary treatment substance as claimed in claim 23 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

28. (Amended) A method of enhancing the therapeutic treatment of an animal, including a human, for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction

with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

30. (Amended) A method as claimed in claim 28 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

31. (Amended) A method as claimed in claim 28 wherein the liquid extract comprises substantially only the water soluble components of the juice.

32. (Amended) A method as claimed in claim 28 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

33. (Amended) A method as claimed in claim 28 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

35. (Amended) A method as claimed claim 28 wherein the primary substance comprises an antibiotic substance.

In accordance with 37 C.F.R. §1.121(c)(1)(ii), please find attached hereto a marked-up version of only those claims which have been amended, showing the changes made by Microsoft Word 2000 redline method.

Remarks

The present Preliminary Amendment is submitted in regard to the US National Stage application of PCT/AU00/01159. Filed concurrently herewith is a form PTO-1390 (Transmittal Letter to the United States Designated/Elected Office(DO/EO/US) concerning a filing under 35 U.S.C. §371) in regard to the above-identified application.

At the outset, it is proposed to amend the specification pursuant to 37 C.F.R. §1.121(b)(1)(i) and (ii) to insert appropriate headings throughout, as more particularly set forth above. It is also proposed by this Preliminary Amendment to add a terminal paragraph, as also set forth herein above, at the end of the detailed description before the claims. The Examiner will please note that the page number and line number locations for these changes to the specification are based upon the specification as it appears in the copy of the published International application under 35 U.S.C. §154(d)(4).

Please note that the amendments to the claims referred to above are based upon the version of the claims as they existed subsequent to the Article 34 Amendment which was made during the International Stage by the Applicant (See Annex pages 11-17 to the International Preliminary Examination Report dated November 13, 2001). More particularly, claims 13-22 are cancelled, claims 4-7, 9-12, 25, 26, 28, 30-33 and 35 are amended, and claims 1-3, 8, 23, 24, 27, 29, 34 and 36-37 remain unchanged. Accordingly, claims 1-12 and 23-37 now remain in this application. The claim fees as set forth in form PTO-1390 are calculated pursuant to the amendments to the claims made in the present Preliminary Amendment.

However, the Commissioner is hereby authorized to charge any deficiency in the payment of the required fee(s) or credit any overpayment to Deposit Account No. 13-1940.

Applicant respectfully requests that the Examiner enter an allowance of all claims in this case. Action to that end is courteously solicited. If any issues remain to be resolved prior to granting of this application, it is respectfully requested that the Examiner contact the undersigned attorney for the Applicant at the number listed below.

Respectfully submitted,

TIMOTHY J. MARTIN, P.C.

Timothy J. Martin, #28,640
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Marked-Up Version of Amended Claims Pursuant To 37 C.F.R. §1.121(c)(1)(ii)

4. (Amended) The use as claimed in ~~any one of the preceding claims~~ claim 1 or claim 2 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

5. (Amended) The use as claimed in ~~any one of the preceding claims~~ claim 1 or claim 2 wherein the liquid extract comprises substantially only the water soluble components of the juice..

6. (Amended) The use as claimed in ~~any one of the preceding claims~~ claim 1 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

7. (Amended) A ~~substance~~ product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the ~~secondary substance~~ product comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

9. (Amended) A ~~substance~~ product as claimed in claim 8 wherein the juice is derived from rye grass (Secale Cereale).

10. (Amended) A ~~substance~~ product as claimed in ~~claim 7, 8 or 9~~ claim 7 or claim 8 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

11. (Amended) A ~~substance~~ product as claimed in ~~any one of claims 7 to 10~~ claim 7 or claim 8 wherein the liquid extract comprises substantially only the water soluble components of the juice.

12. (Amended) A ~~substance~~ product as claimed in ~~any one of claims 7 to 11~~ claim 8 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

25. (Amended) An adjunct secondary treatment substance as claimed in claim 23 ~~or claim 24~~ wherein the liquid extract comprises substantially only the water soluble components of the juice.

26. (Amended) An adjunct secondary treatment substance as claimed in ~~any one of claims 23 to 25~~ claim 23 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

28. (Amended) A method of enhancing the therapeutic treatment of an animal, including a human, ~~e.g.~~ for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable

extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

30. (Amended) A method as claimed in claim 28 ~~or 29~~ wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

31. (Amended) A method as claimed in ~~any one of claims 28 to 30~~ claim 28 wherein the liquid extract comprises substantially only the water soluble components of the juice.

32. (Amended) A method as claimed in ~~any one of claims 28 to 31~~ claim 28 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

33. (Amended) A method as claimed in ~~any one of claims 28 to 32~~ claim 28 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

35. (Amended) A method as claimed ~~any one of claims 28 to 34~~ claim 28 wherein the primary substance comprises an antibiotic substance.

SIDE EFFECTS TREATMENT

This invention relates to processes and products for the treatment of animals, including humans, to reduce side effects associated with other chemical treatment regimes.

The treatment of animals including veterinary treatment of domestic animals, sporting animals such as race horses, and livestock by use of chemical substances (including systemic and local treatments by ingestion, intravenous, and subcutaneous application as well as by external or topical application) frequently leads to undesirable side effects of the treatment regime. There is a very wide range of such side effects such as effects caused by systemic circulation of the treatment substances or caused by by-products or caused by reaction products. Such side effects include for example rashes, headaches, nausea, dizziness, vision difficulties, circulatory problems and disorders, as well as general or local sensations of pain. Other side effects include gastrointestinal problems, e.g. reflux, indigestion, gas production and eructation, constipation, diarrhoea. The side effects can be due to toxic or allergic reactions by the subject as well as being effects of the mechanisms of the substances. For example, the use of antibiotics is frequently associated with digestive problems when taken by ingestion due to the action of the antibiotics in inhibiting or killing normally present and beneficial micro-organisms in the digestive tract.

Antibiotics are frequently prescribed and used in the treatment of animals, including humans, for micro-organism infections, particularly bacterial infections and undesired side effects of the antibiotics of the general kind outlined above are observed. Such side effects frequently require separate treatment, such as treatment with antihistamines to manage mild allergic responses.

The condition known as "chronic fatigue syndrome" or "CFS" is believed to be caused or associated with bacterial infection and is therefore known to be treated with

antibiotics. Undesired side effects are therefore associated with treatment of CFS patients with antibiotics.

The administration of antibiotics to animals, including human patients, both before, during and after surgery or other interventions including intrusive examinations is common. Such administration of antibiotics is carried out to avoid or reduce trauma that may be commonly associated with the procedures. For example, respiratory infections, including bacterial and viral infections, are commonly encountered in post operative patients because patients are more susceptible at such times due to the immune system being compromised or more vulnerable following the traumatic procedures and due also to the condition for which the procedure has been carried out. The administration of antibiotics in such circumstances is a frequently used as a precautionary measure. The antibiotics are frequently administered intravenously together with other substances such as saline solutions, analgesics, sedatives. The administration of antibiotics or other chemical treatments as precautionary or preventative treatments before, during or after traumatic events or during immuno compromised or vulnerable conditions can be associated with the undesired side effects of the kind discussed above.

It is an object of the present invention to provide methods and products for reducing the incidence or severity of undesired side effects associated with chemical treatments of animals, including humans.

According to the present invention there is provided a method of treating an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary

treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

The treatment of an animal, including a human, with a primary treatment substance having undesirable side effects with the secondary substance as an adjunct to the primary treatment is based on the unexpected and surprising reduction of the incidence or severity of the side effects resulting apparently from the adjunct treatment. For example, it has been observed that in the treatment of CFS using antibiotics, the normally or occasionally expected and observed side effects of the antibiotic treatment regime were significantly reduced in subjects having the adjunct treatment with the secondary substance according to the process of the present invention.

Likewise, it has been observed that the treatment of race horses for injured or pathological conditions involving administration of chemical substances such as antibiotics, has frequently necessitated the horses being rested or "spelled" or "turned out" for several months due to side effects of the primary treatment. However the administration of a secondary substance in accordance with the present invention to the animals as an adjunct to

the primary treatment has surprisingly led to horses following thorough veterinary inspections being declared fit to be raced again after much shorter resting or spelling periods.

Broadly the secondary substance used in the present invention comprises a pharmaceutically acceptable liquid extract from a juice derived from cereal plants (which includes wild grasses) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject. Such a substance will be referred to in this specification as "a substance of the kind described".

The references throughout this specification to a primary chemical treatment are intended to cover any treatment with a foreign substance or material, whether by external, topical, transdermal, subcutaneous, intravenous application or by ingestion, the foreign substance or material including pharmaceuticals, herbal or naturopathic substances, and organic and inorganic elements or compounds, and carriers or excipients therefor.

According to a first particular aspect of the present invention, there is provided a novel use of the substance of the kind described for the manufacture of a product for the adjunct treatment of animals including humans, to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

According to a second particular aspect of the present invention there is provided a product for the adjunct treatment of animals, including humans, the product comprising a substance of the kind described in an effective quantity to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

In a third particular aspect of the present invention there is provided a process for the adjunct treatment of animals, including humans, undergoing a primary chemical treatment, the process including the steps of administering an effective quantity of a substance of the

kind described to the animal in a manner and over a period of time to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

In accordance with a fourth particular aspect of the present invention there is provided an adjunct secondary treatment product effective to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal, the product comprising a substance of the kind described provided in a concentration and medium for administration to the animal to achieve the side effect reduction.

In a fifth particular aspect of the present invention there is provided a process for enhancing a therapeutic treatment of an animal by reducing the incidence or severity of side effects associated with a primary chemical treatment of the animal, the process comprising administering to the animal a substance of the kind described in a quantity and over a period of time to be effective to achieve the side effect reduction.

Preferably in the processes of the invention the administration of the adjunct secondary treatment substance occurs simultaneously with, and may also be continued after, the primary chemical treatment period.

A substance of the kind described is already known from Australian patent specification No. AU-81985/87 (Patent No. 599725) (equivalent US Pat. No. 4,943,433) by the present applicant. In this prior patent specification, a range of possible uses of the substance are described or indicated in passing. This earlier patent specification and subsequent uses of the commercial product produced according to the prior patent specification have resulted in recognition of range of physiological indications including anti-inflammatory, immunomodulatory, and analgesic activity. However, the activity of the substance of the kind described to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal is totally unexpected and surprising leading

to novel new uses of the substance hitherto unknown and with no reason to expect or suspect or seek such new uses.

Reference may be made to AU-81985/87 for further background and description of a substance of the kind described useable in the present invention in its various aspects. References herein to "cereal plants" is to be interpreted to include wild grasses. However, a particular cereal plant found to be particularly useful as a source of the extract is *Secale Cereale* or "rye grass".

Extracts from barley and wheat are also believed to be effective. The wheat may comprise Triticum vulgare or aestivum, T. durum, T. compactum, or triticale. Corn, rice, oats, maize, sorghum and millet may also be effective.

Preferably the extract is derived from the green leafy part of the plant, or at least principally from this part of the plant, although additional green parts such as stalk may be included. The leaves of the plant are preferably treated to yield the extract before the plant reaches flowering or seed production stage of development. That is, the plant is at its unjointed or immature development stage.

The extraction is preferably carried out by squeezing, crushing and/or grinding processes, not by a cutting process.

Preferably the extract from the cereal plants comprises substantially only the water soluble components of the juice.

The plant extract may be used in the concentration in which it is derived from the plants. Alternatively, if desired, the extract may be concentrated and some or substantially all the liquid content of the plant extract may be removed. For example, the extracted plant matter may be dried, such as by spray drying to yield a powder for mixing with the carrier.

The spray drying is preferably carried out at a temperature of about 50°C and preferably below 60°C.

Other possible stabilisation processes for the juice include partial concentration of the derived juice to provide a concentrated liquid, freeze drying of the derived juice, and blending the derived juice with a preserving agent forming an ingredient of the carrier.

Preferably the stabilisation or mixing with the carrier or both is carried out within a short time and preferably within two hours after extraction.

In an alternative possibility the extract may be produced by firstly drying plant matter after which the dried material is comminuted to yield a powder which includes ingredients originally in the juice.

The carrier for the extract may be any suitable material such as a liquid (e.g. water or other solvent), cream, lotion, oil, gel or powder. For example the carrier may comprise a liquid in which the extract is dissolved or vanishing cream which is intended to be absorbed through the skin when applied so as to thereby carry the plant extract into sub-cutaneous tissue. A water based or aqueous carrier capable of carrying water soluble ingredients to sub-surface tissues is preferred. Benzyl alcohol is a suitable carrier component for transdermal take up of the active ingredients.

The carrier for the extract may comprise the same carrier as used for the primary chemical treatment. For example, antibiotics can be administered to an animal in a lotion or cream to be applied topically or externally. In such a case the substance of the kind described can be mixed with the primary treatment substance in the same carrier for simultaneous administration. Likewise, antibiotics or other primary treatment substances can be administered intravenously and, subject to obvious precautions concerning composition and concentrations, the substance of the kind described can be mixed with the

intravenous solution for simultaneous administration. Of course, it will be appreciated that the primary treatment substance and secondary treatment substance can be administered separately in their respective carriers. e.g. the primary substance intravenously and the secondary substance transdermally, or the primary substance by ingestion and the secondary substance by sublingual administration and transdermal absorbtion through oral mucous tissues.

Preferably the carrier includes an anti-microbial agent so as to kill or at least inhibit growth, reproduction or activity of contaminating organisms that may be present in the plant extract or may be introduced during production of the substance. Preferably the anti-microbial agent is an anti-bacterial agent. In addition or alternatively the agent may have anti-fungal and anti-yeast properties. The anti-microbial agent may be added to the substance during production or may be present in the carrier if the carrier for example is a standard commercially available product. The anti-microbial agent is preferably active to inhibit any activity of organisms and thereby is operative to inhibit spoilage of the substance, e.g. spoilage of the product when being stored by the user or by a commercial outlet.

If the anti-microbial is not provided, it is preferred that the extract is substantially sterile when mixed with the carrier. The plants from which the extract is derived may be grown hydroponically for example under sterile conditions to prevent the introduction of micro-organisms at that stage. The subsequent harvesting and processing may also be carried out under sterile conditions.

The ratio of the extract to the carrier may be anywhere within a large range of possible ratios. For example the ratio of base carrier to plant extract (and other additives if

provided) may be anywhere between 1 to 5 and 200 to 1 (by weight). A range of 1 to 30% by weight of extract is preferred.

Preferably the substance has a generally neutral pH in the range 6.0 to 8.0. For example, the pH may be in the range 6.5 to 7.5.

Use of the substance of the kind described to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal is preferably by external application so that the substance is taken up by the body by absorption through the skin or mucous tissues. A particularly preferred method of transdermal uptake is by applying the substance to the mouth for uptake through mucous tissues of the mouth. For example, the substance may be administered sublingually, e.g. in the form of drops of the substance taken orally and held in the mouth under the tongue for a short time. It is found that this method of administration is effective for uptake of the substance into the body. A suitable formulation is available commercially under the registered trade mark Oralmat, manufactured by Schumacher Pharmaceuticals Pty Ltd of Melbourne, Australia. This formulation can be taken sublingually, three drops taken three times daily, to achieve the described beneficial effects.

It may also be possible (subject to obvious safeguards concerning the composition and concentration of the substance and carrier) to administer the substance subdermally by implant or injection.

The reduction of the incidence or severity of side effects associated with primary chemical treatment of the animal was unexpected and surprising and as yet the mechanism for this activity has not been determined. Indeed no obvious possible mechanism for the observed side effect reducing activity appears from the known physiological activities of the

substance according to the prior patent specification AU-81985/87 which have been seen over about the last ten years that might have suggested or predicted that activity.

The described effects of reducing incidence or severity of side effects have been observed in use of the secondary substance as a simultaneous adjunct treatment of patients being treated for chronic fatigue syndrome with a primary treatment substance in the nature of an antibiotic.

The accelerated recovery with reduced or shortened incidence or severity of side effects has been observed in race horses undergoing primary chemical treatment for injury or pathological conditions.

These observed examples of reduction of the incidence or severity of side effects in chronic fatigue syndrome patients and in race horses indicate applicability of the present invention as an adjunct treatment for an animal, including a human, being treated for a pathological or injured or abnormal condition involving administration of a primary chemical treatment, particularly antibiotics. However, the observed advantageous effects in side effects reduction indicates that the present invention is also applicable as a precautionary or preventative treatment, e.g. before, during or after a traumatic event or before, during or after an observed or expected immuno compromised or vulnerable condition, e.g. pre or post operative periods. The adjunct treatment of an animal according to the present invention promises a substantial reduction or amelioration of side effects in such circumstances.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

2. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, wherein the product includes a primary substance used for the primary chemical treatment and a secondary substance, the primary substance being mixed in the same pharmaceutically acceptable carrier or excipient as the secondary substance the secondary substance comprising a pharmaceutically acceptable extract from a juice derived from cereal plants.

3. The use as claimed in claim 2 wherein the juice is derived from rye grass (Secale Cereale).

4. The use as claimed in any one of the preceding claims wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

5. The use as claimed in any one of the preceding claims wherein the liquid extract comprises substantially only the water soluble components of the juice.

6. The use as claimed in any one of the preceding claims wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

8. A product for the treatment of animals including humans including a primary substance used for a primary chemical treatment of the animal and a secondary substance for the adjunct treatment of the animal to reduce the incidence or severity of side effects associated with the primary chemical treatment, the primary substance being mixed in the same carrier or excipient as the secondary substance, the second substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants, whereby both the primary substance and the secondary substance are administered to the subject simultaneously.

9. A substance as claimed in claim 8 wherein the juice is derived from rye grass (Secale Cereale).

10. A substance as claimed in claim 7, 8 or 9 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

11. A substance as claimed in any one of claims 7 to 10 wherein the liquid extract comprises substantially only the water soluble components of the juice.

12. A substance as claimed in any one of claims 7 to 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

13. A method of precautionary or preventative treatment of an animal, including a human, of side effects associated with a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

14. A method as claimed in claim 13 wherein the juice is derived from rye grass (Secale Cereale).

15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.

17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

19. A method as claimed in claim 18 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

20. A method as claimed any one of claims 13 to 19 wherein the primary substance comprises an antibiotic substance.

21. A method as claimed in claim 20 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

23. An adjunct secondary treatment substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to

and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.

24. An adjunct secondary treatment substance as claimed in claim 23 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

25. An adjunct secondary treatment substance as claimed in claim 23 or claim 24 wherein the liquid extract comprises substantially only the water soluble components of the juice.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

27. An adjunct secondary treatment substance as claimed in claim 26 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

28. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a

secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

29. A method as claimed in claim 28 wherein the juice is derived from rye grass (Secale Cereale).

30. A method as claimed in claim 28 or 29 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

31. A method as claimed in any one of claims 28 to 30 wherein the liquid extract comprises substantially only the water soluble components of the juice.

32. A method as claimed in any one of claims 28 to 31 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

33. A method as claimed in any one of claims 28 to 32 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

34. A method as claimed in claim 33 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

35. A method as claimed any one of claims 28 to 34 wherein the primary substance comprises an antibiotic substance.

36. A method as claimed in claim 35 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

37. A method as claimed in claim 35 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

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(54) Title: SIDE EFFECTS TREATMENT

(57) Abstract: The invention provides a novel use of a substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants (which includes wild grasses) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject. The use is for the manufacture of a product for the adjunct treatment of animals including humans, to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal. The invention also provides a product for the adjunct treatment of animals, a process for the adjunct treatment of animals, an adjunct secondary treatment product effective to reduce the incidence or severity of side effects, and a process for enhancing the therapeutic treatment of an animal.

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	1805
First Named Inventor	David Rudov
COMPLETE IF KNOWN	
Application Number	
Filing Date	09/25/2000
Art Unit	
Examiner Name	

As the below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SIDE EFFECTS TREATMENT

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 09/25/2000 as United States Application Number or PCT International

Application Number PCT/AU00/01159 and was amended on (MM/DD/YYYY) 03/22/2002 (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
PQ 3050	Australia	09/24/1999	☐	☐	☑
PQ 4064	Australia	11/16/1999	☐	☐	☑
			☐	☐	☐
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First Named Inventor	David Rudov
Title	SIDE EFFECTS TREATMENT
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Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	David Rudov
Signature	X DRudov
Date	X 10/7/2002

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